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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,017	01/14/2004	Heinrich Kladders	01-1448	3319
<sup>28501</sup> MICHAEL P. N	7590 06/25/200 MORRIS	EXAMINER		
BOEHRINGER INGELHEIM USA CORPORATION			PATEL, NIHIR B	
P. O. BOX 368	000 RIDGEBURY ROAD P. O. BOX 368		ART UNIT	PAPER NUMBER
RIDGEFIELD, CT 06877-0368			3772	
			MAIL DATE	DELIVERY MODE
			06/25/2008	PAPER

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
Office Action Comments	10/757,017	KLADDERS ET AL.				
Office Action Summary	Examiner	Art Unit				
	NIHIR PATEL	3772				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	<b>J.</b> nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 03.07	7.2008.					
	· · · · · · · · · · · · · · · · · · ·					
3) Since this application is in condition for allowan	ice except for formal matters, pro	secution as to the merits is				
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	i3 O.G. 213.				
Disposition of Claims						
4)⊠ Claim(s) <u>1 and 3-20</u> is/are pending in the application.						
	4a) Of the above claim(s) is/are withdrawn from consideration.					
5)⊠ Claim(s) <u>9 and 16-20</u> is/are allowed.						
6)⊠ Claim(s) <u>1, 3-8 and 10-15</u> is/are rejected.	· <u> </u>					
7) Claim(s) is/are objected to.						
· · · · · · · · · · · · · · · · · · ·						
are subject to restriction and of	olootion roquiromone.					
Application Papers						
9)☐ The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date	4)  Interview Summary Paper No(s)/Mail Da 5)  Notice of Informal P 6)  Other:	ate				

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### **DETAILED ACTION**

## Response to Arguments

1. Applicant's arguments filed on March 7<sup>th</sup>, 2008 have been fully considered but they are not persuasive. The applicant argues that Jaeger does not disclose or suggest the elevation and/or depression microstructures and/or nanostructures. The examiner disagrees with the applicant's argument. The fact that the Jaeger reference states that the direction of the spray may be inclined inherently imply that there is elevation and/or depression microstructures and/or nanostructures.

# Response to Amendment

2. The examiner acknowledges the amendment filed on March 7<sup>th</sup>, 2008. The amendment comprises the cancellation of claim 2 and amendment to claims 1 and 7. No new claims have been added.

#### Allowable Subject Matter

3. Claims **9 and 16-20** are allowed. The prior art does not teach or suggest a check nut engaging the nozzle holder and having an end face and a bore including a side wall thereof, which communicates with the through-bore of the nozzle holder and widens out continuously therefrom, wherein at least one of an outer surface of the end face of the check nut and the side wall of the bore of the check nut include at least one of microstructures and nanostructures.

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## Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 5. Claims **1, 3-8 and 10-15** are rejected under 35 U.S.C. 102(b) as being anticipated by Jaeger et al. (WO 97/12687).
- 6. As to claims 1 and 12, Jaeger teaches a device of miniaturized construction for producing high pressure in a fluid to be atomized that comprises a nozzle 54 for a delivery device for fluids comprising an inlet side and an outlet side, the outlet including at least one nozzle opening; wherein the outer surface of the outlet side includes at least one of elevation and/or depression microstructures and nanostructures, which do not include the at least one nozzle opening (see page 9 beginning last paragraph continued on page 10 lines 1-10).
- 7. As to claim 3, Jaeger teaches an apparatus that comprises at least two nozzle openings oriented so that the jets of fluid emerging from them intersect (In a nozzle member having at least two nozzle openings at the outlet end, the directions of spray may be inclined relative to one another at an angle from 20 to 160 degrees, preferably at an angle 60 to 150 degrees. The directions of spraying meet in the vicinity of the nozzle openings" (see page 10 first full paragraph). This implies that the jets of fluid would intersect).
- 8. **As to claim 4,** Jaeger teaches an apparatus wherein the nozzle is formed from at least two constructional units (The nozzle member consists of two plates of glass and/or silicon firmly

joined together (see page 9 fourth paragraph). Each plate of glass being a constructional unit makes it two constructional units).

9. **As to claim 5,** Jaeger teaches an apparatus wherein the constructional units comprise superimposed plates, at least one of the plates produced by microtechnology, so that the plates lying one on top of the other define, on one side, a fluid inlet connected to a channel system and/or a filter system which then opens into one or more fluid outlets (see page 9 fourth paragraph).

This is a product-by-process where the product is the superimposed plates lying one on top of the other define, on one side, a fluid inlet connected to a channel system and/or a filter system which then opens into one or more fluid outlets. The process or method of production is microtechnology.

Even though product-by-process claims are limited by and defined by the process, determination or patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. *In re Thorpe*, 777 F.2d. 695, 227 USPQ 964, 966 (Fed. Cir. 1985).

- 10. **As to claim 6,** Jaeger teaches an apparatus wherein the nozzle has at least two nozzle outlets oriented towards one another (see page 10 first full paragraph).
- 11. **As to claim 7,** Jaeger teaches a device of miniaturized construction for producing high pressure in a fluid to be atomized that comprises a nozzle **54** having one or more nozzle openings and an outer surface at a fluid outlet side of the nozzle (see page 9 beginning last paragraph

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continued on page 10); a nozzle holder 53 which comprises a through-bore having a sidewall initiating at a position in communication with the one or more nozzle openings of the fluid outlet side of the nozzle, and terminating at an end face of the nozzle holder; wherein at least one of the following surfaces includes at least one of microstructures and nanostructures, which do not include the one or more nozzle openings (see page 9 beginning last paragraph continued on page 10): the outer surface of the fluid outlet side of the nozzle, an outer surface of the end face of the nozzle holder, or the side wall of the through –bore of the nozzle holder.

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- 12. **As to claim 8,** Jaeger teaches an apparatus wherein the through-bore 7 of the nozzle holder 53 widens out 33 from one or more nozzle openings to the end face thereof (see figure 1).
- 13. **As to claim 10,** Jaeger teaches an apparatus wherein a side of the through bore 7 that is remote from the one or more nozzle openings includes at least one of microstructures and nanostructures (see page 9 beginning last paragraph continued on page 10).
- 14. **As to claim 11,** Jaeger teaches an apparatus wherein the nozzle comprises an outlet side and an inlet side (see page 9 beginning last paragraph continued on page 10).
- 15. As to claim 13, Jaeger teaches an apparatus that comprises a nozzle system (see figure1).
- 16. As to claim 14, Jaeger teaches an apparatus that comprises a lower 70 and upper 51 housing part mounted to be rotatable relative to one another, the upper part of the housing containing a spring housing 67 with a spring 68 which is tensioned by rotating the two housing parts by means of a locking clamping mechanism 62 and is released by pressing a release button 64 on the upper part of the housing, the spring moving a power take-off flange 56 connected to a piston 57 on the lower end of which a container can be fitted, and at the upper end of which are

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found a valve **58** and a pressure chamber **4** which is connected for fluid transmission to the nozzle system formed in the upwardly open part of the upper housing part (see page 17 paragraph **4**).

17. **As to claim 15,** Jaeger teaches an apparatus wherein the device is an inhaler atomizer for delivering medicinal or pharmaceutical fluids (see page 3 paragraph 1).

### Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

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like assistance from a USPTO Customer Service Representative or access to the automated

information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/

Examiner, Art Unit 3772

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772